



## NUCLEAR REGULATORY COMMISSION

### 10 CFR Part 32

[Docket No. PRM-32-7; NRC-2012-0127]

#### Compatibility of Generally Licensed and Exempt Devices

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Petition for rulemaking; denial.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is denying a petition for rulemaking (PRM), dated May 7, 2012, submitted by Mr. Sean Chapel (the petitioner) on behalf of the Association of Device Distributors and Manufacturers (ADDM). The petition was docketed by the NRC on May 24, 2012, and was assigned Docket No. PRM-32-7. The petitioner requested that the NRC create a new regulation for exempt devices similar to the NRC's regulations for generally licensed devices. The petitioner also requested that the NRC change the Agreement State compatibility designation of the regulations applicable to generally licensed devices that are specified in § 31.6 of Title 10 of the *Code of Federal Regulations* (10 CFR) from "C" to "B". The NRC is denying the petition because the petitioner failed to present any significant new information or arguments that would support the requested changes, nor has he demonstrated a need for a new provision for exempt devices.

**DATES:** The docket for the petition for rulemaking, PRM-32-7, is closed on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** Please refer to Docket ID NRC-2012-0127 when contacting the NRC about the availability of information for this petition. You may access publicly-available information related to this petition by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov> and search for Docket ID NRC-2012-0127. Address questions about NRC dockets to Carol Gallagher; telephone: 301-287-3422; e-mail: [Carol.Gallagher@nrc.gov](mailto:Carol.Gallagher@nrc.gov). For technical questions, contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **NRC's Agencywide Documents Access and Management System (ADAMS):**  
You may access publicly available documents online in the NRC Library at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "[ADAMS Public Documents](#)" and then select "[Begin Web-based ADAMS Search](#)." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov). The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced. The petition, PRM-32-7, is available in ADAMS under Accession No. ML12146A083.

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

**FOR FURTHER INFORMATION CONTACT:** Solomon Sahle, Office of Federal and State Materials and Environmental Management Program, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-3781, e-mail: [Solomon.Sahle@nrc.gov](mailto:Solomon.Sahle@nrc.gov).

**SUPPLEMENTARY INFORMATION:**

## **I. The Petition.**

Section 2.802 of 10 CFR, "Petition for rulemaking," provides an opportunity for any interested person to petition the Commission to issue, amend, or rescind any regulation. On May 7, 2012, the NRC received a PRM from Mr. Sean Chapel on behalf of the ADDM. The PRM contained two requests.

The petitioner's first request was "that language similar to 10 CFR 31.6 be included in section 10 CFR [part] 32 to include the servicing of exempt devices, since these are within the jurisdiction of the NRC." The petitioner further asserted that "[i]t does not make sense that generally licensed devices can be serviced without filing for reciprocity, but exempt devices, which have a lower radiation dose potential, [cannot] be." The petitioner suggested the following language for 10 CFR part 32:

"Any person who holds a specific license issued by an Agreement State authorizing the holder to manufacture, install or service a device described in [§§] 32.14, 32.22, or 32.26 within such Agreement State is hereby granted a general license to install and service such device in any non-Agreement State and a general license to install and service such device in offshore waters, as defined in § 150.3(f) of this chapter; [p]rovided [t]hat:

- (a) Reserved[.]
- (b) The device has been manufactured, labeled, installed and serviced in accordance with the provisions of the specific license issued to such person by the Agreement State.
- (c) Such person assures that any labels required to be affixed to the device under regulations of the Agreement State which licensed manufacture of the device bear a statement that removal of the label is prohibited."

The petitioner's second request was that the NRC change the compatibility designation of 10 CFR 31.6, "General license to install devices generally licensed in § 31.5," from "C" to "B." The petitioner's basis for the request for compatibility change was that "inconsistent application of individual Agreement State regulations and policies places an unreasonable burden on licensees to maintain compliance." Further, the petitioner stated that in 2000, the NRC changed the compatibility of 10 CFR 31.6 from "C" to "B" "in acknowledgement of the problems caused by incompatible State reciprocity regulations."

The petitioner stated that “[t]he Commission voted to decrease the compatibility in December 2010, stating that they thought it appropriate for Agreement States to regulate devices in their jurisdiction as they saw fit.” The petitioner asserted that “[i]n the Commission ruling, there is no evidence that they fully reviewed the original decision in 2000 to increase the compatibility rating.”

The petitioner stated that “reciprocity regulations must be standardized at the national level” to avoid the chaos that “would be caused if each state had different regulations for occupational radiation doses, nuclear power plant operation, or high and low level radioactive waste.” The petitioner asserted that “[t]his is the type of disorder that reciprocity applicants are forced to endure on a daily basis.” The petitioner stated that “[t]he NRC should enforce these requirements as part of the IMPEP [Integrated Materials Performance Evaluation Program] review process.” The petitioner further stated “that there are several Agreement States which have adopted 10 CFR 31.6, but do not implement the regulations as they are written, and still require reciprocity to be filed.” In reference to the change in compatibility, the petitioner is “not asking that the regulations be re-written, only that they be enforced as written.”

In support of the second request, the petitioner cited a PRM dated June 27, 2005 (ADAMS Accession No. ML051940187), from the Organization of Agreement States (OAS), which requested that the compatibility of 10 CFR 31.6 be revised from “C” to “B.” The petitioner also noted that the OAS petition “stated that the reason for changing the compatibility of 10 CFR 31.6 was to assist the tracking and movement of companies and individuals that service these devices.” The NRC staff asked the petitioner, by telephone, to clarify that the reference was to an OAS PRM requesting that the compatibility of 10 CFR 31.6 be revised from “B” to “C,” and if so, to resubmit a letter correcting his PRM. By letter dated August 3, 2012 (ADAMS Accession No. ML12219A085), the petitioner corrected his reference to the OAS PRM.

## **II. Discussion.**

### *Reciprocity for Exempt Devices*

Section 31.6 of 10 CFR provides a general license to persons holding a specific license issued by an Agreement State that authorizes manufacture, installation, or servicing of a device described in 10 CFR 31.5 to install and service these devices in any non-Agreement State and in offshore waters. The NRC adopted this regulation in 1962 (originally in 10 CFR 30.21(c)(6)) at the same time 10 CFR part 150, “Exemptions and Continued Regulatory Authority in Agreement States and in Offshore Waters Under Section 274,” was issued as part of implementing the Agreement State program.

In accordance with 10 CFR 150.15(a)(6), only the NRC can issue licenses for the manufacture, processing, or production of any equipment, device, commodity, or other product containing source material or byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from licensing and regulatory requirements. Therefore, the Agreement States do not issue licenses to manufacture, install, or service exempt devices. Further, servicing exempt devices does not require a license. Any refurbishing not covered by the exemption, such as replacement of a source in a device, would require an NRC license and/or an Agreement State license. Therefore, a general license is not required to install or service exempt devices, and the petitioner’s requested change to the regulations is not needed.

### *Compatibility of 10 CFR 31.6*

On January 25, 2012, the NRC published a *Federal Register* notice (FRN) (77 FR 3640) to withdraw a proposed rule and to close PRM-31-5 (NRC-2005-0018; NRC-2008-0272). PRM-31-5 requested that the NRC amend its regulations to strengthen the regulation of radioactive materials by requiring a specific license for higher-activity devices that are currently available under a general license and by changing the compatibility designation of 10 CFR 31.6

from category “B” to category “C.” In this FRN, the NRC also addressed a related request filed by the Florida Department of Health, Bureau of Radiation Control, in conjunction with the OAS petition to change the compatibility category of a certain part of the applicable regulations from category “B” to category “C.”

In response to PRM-31-5, the NRC developed a proposed rule that would have limited the quantity of byproduct material contained in a generally licensed device to below one-tenth of the International Atomic Energy Agency Category 3 thresholds. It would also have changed the compatibility of the applicable regulations.

The compatibility change requested in PRM-31-5 was filed in response to the 2000 general license rule (65 FR 79162; December 18, 2000), which designated the requirements in 10 CFR 31.5 and 10 CFR 31.6 as compatibility category “B.” The general license rule adopted compatibility “B” for these regulations because the Commission was concerned that essentially identical regulations were needed to ensure reciprocal recognition of licenses and licensing requirements among Agreement States and the NRC. After evaluating the post-2000 general license regulations in response to PRM-31-5, the NRC reassessed its position. The NRC found that since 2000, Agreement States took a variety of actions that were not consistent with the rule, despite its designation as compatibility category “B.” Many Agreement States adopted stricter regulations of generally licensed devices, including registration with annual reporting requirements and periodic inspection; expanded registration of more types of generally licensed devices; specific licensing of certain generally licensed devices; and specific licensing of all generally licensed devices currently registered by the NRC. However, the NRC did not observe any transboundary problems from these different practices that would have supported the continued use of compatibility “B” for 10 CFR 31.5 and 31.6. Further, complexity and cost are not aspects of determining significant transboundary health and safety impacts under the Commission’s 1997 Policy Statement on Adequacy and Compatibility of Agreement State Programs (62 FR 46517; September 3, 1997). Therefore, the NRC believed it was appropriate

to change the compatibility category from “B” to “C” for 10 CFR 31.5 and 10 CFR 31.6. This action allowed many Agreement States to continue the practices they had already implemented and to take additional steps they deem appropriate based on local circumstances, including retaining the use of tools to track the location and movement of devices, manufacturers, and service providers within the State; addressing issues specific to their jurisdictions; continuing programs that have proven beneficial; and adopting requirements based on their specific circumstances and needs.

After further review, the Commission addressed the compatibility-related issues raised in PRM-31-5. Although the Commission disapproved publication of the final rule and withdrew the proposed rule, it approved the change in compatibility for 10 CFR 31.5 and 10 CFR 31.6. The Commission also directed the staff to assess the degree to which the Agreement States modify their programs as a result of the change in compatibility category and to analyze any transboundary impacts to regulated entities, particularly those operating in multiple jurisdictions. If transboundary problems are identified, the staff will suggest corrective actions that may be necessary (ADAMS Accession No.ML103360262). The Commission also planned to consider proposed updates to the Policy Statement on Adequacy and Compatibility of Agreement State Programs and associated guidance documents to include both safety and source security considerations in the determination process. The NRC closed PRM-31-5 because all of the petitioners’ requests had been resolved.

As previously discussed, the NRC is denying this portion of the petitioner’s request because the compatibility of § 31.6 was recently and thoroughly addressed in the response to PRM-31-5, and the NRC is not aware of any new information that would cause it to reevaluate this decision.

### **III. Conclusion.**

The NRC is denying PRM-32-7 because the petition did not present a need for any revision of the regulations to add a general license for installation and servicing of exempt devices. The petition failed to present any significant new information or arguments that would warrant the requested amendment. The NRC elected not to request public comment on PRM-32-7 because no new regulation is necessary to accomplish the petitioner's request; accordingly, there were no public comments on this petition.

As to the additional request for a compatibility change for 10 CFR 31.6, the issues concerning this categorization were considered and addressed by the Commission in a recent decision (77 FR 3640; January 25, 2012). The Commission will not reconsider that decision at this time in the absence of new information that warrants the requested change.

For the previously cited reasons, the NRC is denying PRM-32-7.

Dated at Rockville, Maryland, this 10<sup>th</sup> day of September 2013.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,  
Secretary of the Commission.

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